

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0583]

Food Security Guidance; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB
01-04-02 @ 4:12 p.m.
01-09-02
A. Corbin

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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of two guidance documents related to food security entitled "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance." "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" is designed as an aid to operators of food establishments (i.e., firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients, or that prepare or distribute food at retail). It identifies the kinds of preventive measures that they can take to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions. "Importers and Filers: Food Security Preventive Measures Guidance" is designed as an aid to operators of food importing establishments, storage warehouses, and filers. It identifies the kinds of preventive measures that they can take to minimize the risk that food under their control will be subject to tampering or criminal or terrorist actions.

DATES: Submit written or electronic comments by *[insert date 60 days after date of publication in the Federal Register]* to ensure their adequate consideration in the preparation of revised guidance, if warranted. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" or "Importers and Filers: Food Security Preventive Measures Guidance" to John Kvenberg, Office

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of Field Programs (HFS–600), Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Include a self-addressed adhesive label to assist that office in processing your request.

Submit written comments on the guidance documents to Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance documents.

FOR FURTHER INFORMATION CONTACT: John Kvenberg, Office of Field Programs (HFS–600), CFSAN, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202–205–4187, e-mail: jkvenberg@cfsan.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Operators of food establishments, food importing establishments, and filers are encouraged to review their current procedures and controls in light of the potential for tampering or criminal or terrorist actions and make appropriate improvements. “Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance” aids operators of food establishments (i.e., firms that produce, process, store, repack, relabel, distribute, or transport food or food ingredients, or that prepare or distribute food at retail). It is relevant to all sectors of the food system (i.e., from farm-to-table), including farms, aquaculture facilities, fishing vessels, producers, transportation operations, processing facilities, packing facilities, warehouses, retail, and food-service establishments. “Importers and Filers: Food Security Preventive Measures Guidance” aids operators of food importing establishments, storage warehouses, and filers. Both guidance documents identify the kinds of preventive measures that operators can take to minimize the risk that food under their control will be subject to tampering or to criminal or terrorist actions. They take the operator through each segment of the farm-to-table system that is within their control, in order to minimize the risk of tampering or of criminal or terrorist action at each segment.

Implementation of these measures requires commitment from both management and employees to be successful and, therefore, both should participate in their development and review.

The two guidance documents are level 1 guidances issued consistent with FDA's good guidance practices regulation (GGPs) (21 CFR 10.115). The agency is soliciting public comment, but is implementing these two guidance documents immediately in accordance with § 10.115(g)(2) (21 CFR 10.115(g)(2)). The two guidance documents were prompted by the tragedies of September 11, 2001, and the resulting scrutiny of, and interest in, food safety and security that followed. FDA believes it is critical to our national interest and the public health to make guidance on food security available to the food industry quickly. Thus, the agency has determined that prior public participation is not feasible or appropriate.

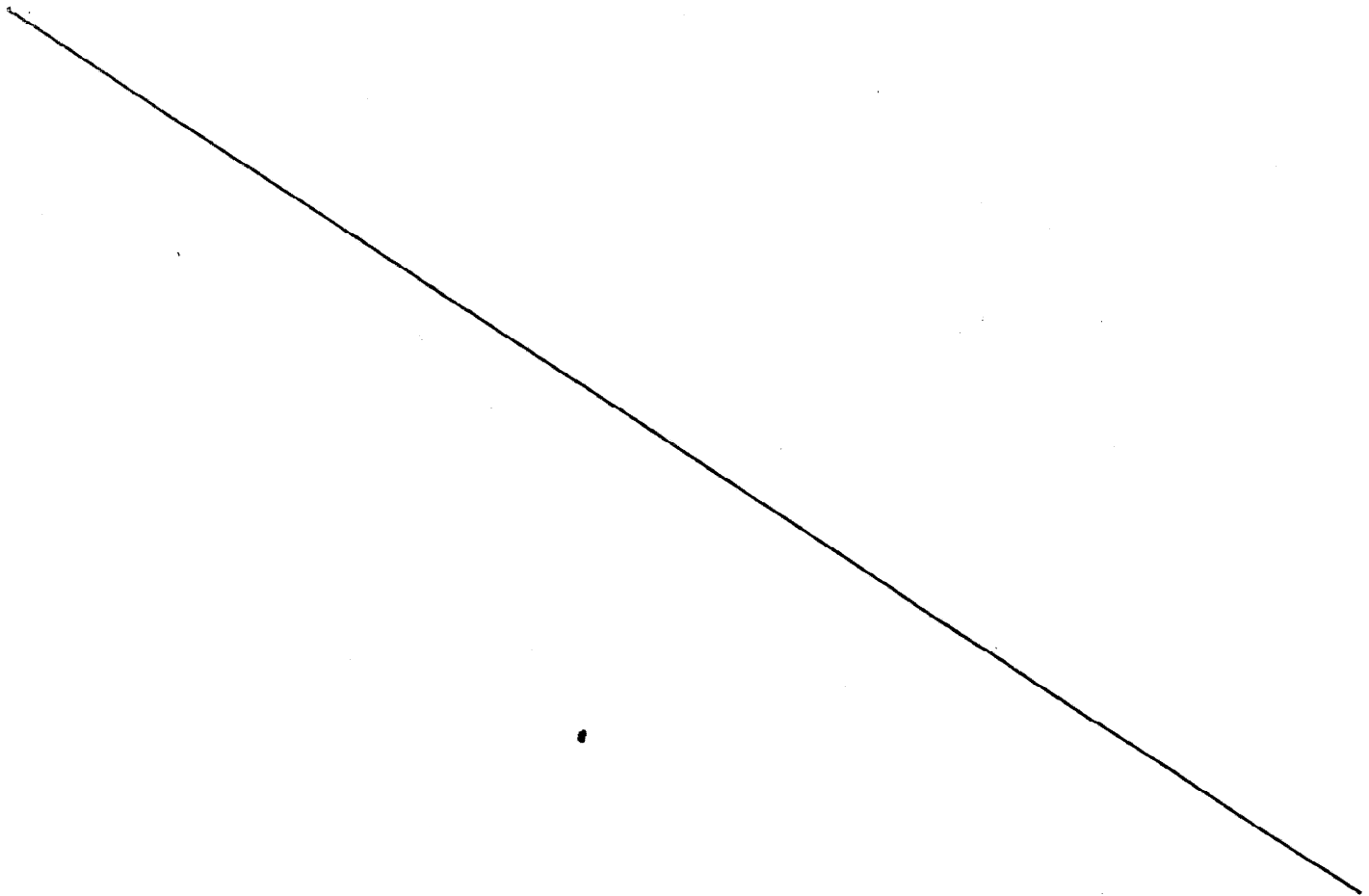
FDA is also interested in comments on whether the guidance documents "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" and "Importers and Filers: Food Security Preventive Measures Guidance" should be revised to include the following additional preventive measures:

- The use of tamper-evident packaging. FDA is particularly interested in information on: the utility of the various methods of tamper-evident packaging in minimizing the risk that foods so packaged will be subject to tampering or criminal or terrorist actions; and, the practicality of applying tamper-evident packaging to the broad spectrum of foods presently in commerce;
- The use of procedures and/or records that enable shipments of food from a food establishment or food importing establishment to be traced to shipments of food received by the food establishment or food importing establishment and vice versa. FDA is particularly interested in information on the types of procedures and/or records that are both practical and effective in facilitating trace-back of incoming shipments, trace-forward of outgoing shipments, and linkages between the two.

These guidance documents represent the agency's current thinking on appropriate measures that can be taken by operators of food establishments, food importing establishments, storage warehouses, and filers to minimize the risk of food being subjected to tampering or criminal or terrorist actions. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public.

II. Comments


Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the guidance documents at any time. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance documents and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Copies of these guidance documents also are available on the Internet at <http://www.cfsan.fda.gov/~dms/guidance.html>. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

Dated: 1/3/02
January 3, 2002.


Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02-???? Filed ??-??-02; 8:45 am]

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